IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

GLAXO GROUP LTD., :

Plaintiff

•

v. : CIVIL NO. AMD 06-469

MICHAEL O. LEAVITT, et al.,
Defendants

...o0o...

MEMORANDUM OPINION SETTING FORTH FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff Glaxo Group, Ltd., sought and obtained a temporary restraining order (TRO), which was secured by a \$3 million bond, enjoining the effectiveness of the approval by the Food and Drug Administration of an application by intervening defendant Roxane Laboratories, Inc. (Roxane), to market fluticasone propionate, the generic form of Glaxo's patented Flonase, the patent for which had expired. Subsequently, after a hearing, I denied Glaxo's motion for a preliminary injunction. Now pending is Roxane's motion for execution on the bond. Herein, I set forth my findings of fact and conclusions of law underlying my determination that Roxane has suffered damages from the TRO and should have execution against the bond.

Findings of Fact

1. On August 7, 2006, I granted Roxane's motion for execution on the bond in a short letter memorandum, but I further concluded that Glaxo was entitled to discovery as to the

precise amount of Roxanne's damages.1

- 2. Roxane presents a compelling case for damages proximately resulting from the grant of the TRO.
- 3. Roxane has sufficiently demonstrated that it suffered damages as a proximate result of the TRO.
- 4. The TRO prevented Roxane from marketing fluticasone for a total of 11 days, causing Roxane to lose profits that it would have otherwise realized.

As to the motion for execution on bond, for the reasons to be detailed in a subsequent order, the motion is GRANTED. *Greewood County v. Duke Power Co.*, 107 F.2d 484 (4th Cir. 1932), is a puzzling case, to be sure, but I am persuaded that when the Fourth Circuit has the opportunity to elucidate its holding in that case, it is almost certain to retreat from any notion that execution on an injunction bond is to be equated with a malicious prosecution action. The court's discussion of *Greenwood County* in *Network International, LC v. Worldcom Tech., Inc.*, 133 F.Supp.2d 713, 718 (D.Md. 2001), is interesting but is purely *dicta*, as the court applied Maryland law in that diversity case.

In any event, I have no hesitation in concluding that even though Judge Bennett acted entirely reasonably in granting the motion for TRO on the bare record before him, and even though Glaxo acted wholly in good faith (in the face of the extended and inexplicable silence from the FDA as to the citizen petitions), the damage to Roxanne from the TRO is real and substantial. In the exercise of the informed discretion the law affords, I shall make an award.

Glaxo is entitled to minimal discovery. Accordingly, on or before October 2, 2006, it may serve up to four interrogatories and four document requests on Roxane. In addition, it may conduct up to four hours of deposition. I am frank to say that Roxane's *prima facie* showing of damages in excess of the bond is compelling, but Glaxo is entitled to examine more closely the bases for the claim. Glaxo shall file a supplemental memorandum on or before October 21, 2006, to which Roxane shall respond on or before November 13, 2006. I shall rule on the papers thereafter.

As to the motion for restitution, the motion is DENIED. This is based on virtually all of the grounds relied on by Glaxo, but I will detail such reasons in a subsequent order.

Letter Order of August 6, 2006.

¹I wrote as follows to counsel:

- 5. This harm is real and substantial for two reasons: (1) at the time of the TRO, Roxane's fluticasone products, which had already been shipped to the retailers, were prevented by the TRO from being sold to consumers; and (2) Roxane has established by the clear weight of the evidence an adequate, if modest, run rate for fluticasone sufficient to reasonably calculate lost profits.
- 6. Glaxo's assertion that Roxane had an insufficient supply of fluticasone necessary to fulfill demand during the pendency of the TRO is not proven.
- 7. Glaxo's contention that, even apart from the TRO, Roxane would not have been able to deliver its product because Roxane experienced a shortage is not proven.
- 8. The TRO prevented customers and patients from buying the stock of fluticasone that had already been sold and shipped by Roxane to its various retailers.
- 9. Prior to the issuance of the TRO, Roxane had already shipped 586,000 units of fluticasone to retailers.
 - 10. While the TRO was in place, retailers could not sell any of the 586,000 units.
- 11. The TRO is the direct cause for Roxane's lost sales in the 11 days that the TRO was in place.
 - 12. Roxane never experienced a shortage of product.²

(continued...)

²Roxane's Marketing Manager, Leslie L. Paoletti, credibly testified that there was never a shortage of fluticasone:

Q. Was it - was it your understanding that any of the salespeople were ever told, don't solicit orders right now because we're running low on inventory? Were there any conversations along those lines?

A. No.

- 13. Roxane did not run a risk of experiencing a shortage: on February 22, 2006, the day of the FDA's approval, Roxane had already manufactured and labeled 932,000 units of fluticasone, all of which were ready for shipment.
- 14. On the same day, Roxane had manufactured an additional 586,000 units, pending only labeling and quality control until shipment, which would have occurred in due course.
- 15. An accurate run rate of 600,000 units/month is reasonable and has been adequately established by Roxanne.³
 - 16. Roxane lost five days of sales in February (which had a total of 28 days).
- 17. Dividing 600,000 units/month by 28 days yields a (rounded) daily rate of 21,429 units/day.
- 18. Thus, in five days, to a reasonable commercial certainty, Roxane would have sold 107,143 units (21,429 units/day x 5).
 - 19. The net profit on fluticasone per unit is \$14.80; accordingly, Roxane lost a total

²(...continued)

Q. Were there ever any conversations where the salespeople were told, you can solicit orders, but just don't solicit huge orders right now because we're running low on inventory?

A. No.

Q. As far as you know, were the salespeople told, go out and solicit orders for as big a shipment as you can get an order for?

A. We wouldn't instruct the sales force to do that.

Q. But as far as you know, none of the salespeople thought there were any constraints on supply?

A. No.

³The run rate employed here is based on (1) the year-to-date average sales after adjustments for initial shipment; (2) data on fluticasone sales for September 2006; (3) the seasonality of the product; and (4) Roxane's reasonably-anticipated increase in sales based on consumer recognition of the product.

- of \$1,585,714.29 in the five days of lost sales in February (107,143 units x \$14.80).
 - 20. Roxane lost six days of sales in March (which had a total of 31 days).
 - 21. Dividing 600,000 units/month by 31 days yields a daily rate of 19,355 units/day.
- 22. Thus, in six days, Roxane would have sold 116,129 units (19,355 units/day times 6 days).
- 23. Roxane lost a total of \$1,718,709.68 in the six days of lost sales in March (116,129 units times \$14.80).
- 24. The injury to Roxane for lost sales in February and March, during the pendency of the TRO, totals \$3,304,423.97.

Conclusions of Law

- 1. While a wrongfully enjoined defendant is not automatically entitled to the full amount of an injunction bond, the defendant may nonetheless recover for damages that naturally and proximately result from the injunction. *Pargas, Inc. v. Empire Gas Corp.*, 423 F.Supp. 199, 244 (D. Md. 1976) (citing *Greenwood County v. Duke Power Co.*, 107 F.2d 484, 488 (4th Cir. 1939)).
- 2. The damages sought "must have been suffered during the period in which the bond was in effect." 11A Wright & Miller, FEDERAL PRACTICE & PROCEDURE § 2973.
- 3. Merely speculative damages are insufficient to trigger execution on an injunction bond. *Network Int'l v. Worldcom Tech., Inc.*, 133 F. Supp. 2d 713, 719 (D. Md. 2001).
- 4. Damages "must be proven with reasonable certainty." *Univ. Lite Dist., Inc. v. Northwest Indus., Inc.*, 602 F.2d 1173, 1175 (4th Cir. 1979).

5. Roxanne has established its entitlement to execute on the bond in the full amount
of \$3 million. ⁴
/s/
ANDRE M. DAVIS UNITED STATES DISTRICT JUDGE

⁴Roxanne is not entitled to a restitutionary measure of recovery. Glaxo did not act wrongfully under the circumstances of this case; indeed, its prompt decision to withdraw its appeal from the denial of the preliminary injunction evidences its good faith. While it is true that Glaxo had sales that it would not have enjoyed during the pendency of the TRO had the TRO not been issued, its right to seek such relief was not exercised maliciously or unlawfully. As an intervening defendant, Roxanne had the right to urge the court to require a bond that was reasonable under the circumstances and it did so.